

Amendments to the Claims:

This listing of claims will replace all prior versions and listings of claims in this application.

Listing of Claims:

1-34. Cancelled

35. (Original) A method of removing contaminants from the pores, lumens and under-the-cap regions of a hemodialyzer including a hollow fiber membrane bundle comprising

backflushing the hollow fiber membrane bundle with a cleaning solution by pressurizing the cleaning solution from the dialysate side of the dialyzer,

passing a gas under pressure into the lumen side of the dialyzer so as to form a two phase flow mixture with the backflushed cleaning solution that produces droplets that create shear or impact stresses on the lumen walls of the hollow fibers, and wherein said two phase flow mixture creates turbulence inside the under-the-cap regions of the hemodialyzer, thereby loosening and removing said contaminants from the dialyzer.

36. (Original) A method according to claim 35 wherein the cleaned dialyzer is rinsed with deionized water and filled with a liquid sterilant.

37. (Original) A method according to claim 35 wherein said cleaning solution includes an agent that unclogs the pores and lumens of the hollow fiber membranes.

38. (Original) A method according to claim 35 wherein said cleaning solution includes a chelating agent.

39. (Original) A method according to claim 35 wherein said cleaning solution is made with sodium hydroxide.

40. (Original) A method according to claim 35 wherein said cleaning solution has a temperature in the range of 20 to 60 degrees Centigrade.

41. (Original) A method according to claim 35 wherein said cleaning solution includes a surfactant.
42. (Original) A method according to claim 35 wherein said cleaning solution has a pH of at least 7.0.
43. (Original) A method according to claim 35 wherein said cleaning solution includes an oxidizing agent selected from the group consisting of a peroxy compound having an acidic pH.
44. (Original) A method according to claim 35 wherein said cleaning solution includes an oxidizing agent selected from the group consisting of a hypochlorite compound.
45. (Original) A method according to claim 35 wherein the direction of the two phase flow is periodically reversed.
46. (Currently Amended) A method according to claim 35 wherein the two phase flow is pulsed by stopping the flow of gas ~~air~~ periodically while backflushing continues.
47. (Original) A method according to claim 35 wherein a pre-mixed liquid-gas two phase flow mixture is applied to the lumen side of the dialyzer prior to commencing the backflushing step.
48. (Currently Amended) A method according to claim 35 wherein the two phase flow cleaning is preceded by backflushing with a cleaning solution ~~liquid~~ alone.
49. (Original) A method of removing contaminants from pores, lumens and under the cap regions of a hemodialyzer including hollow fibers comprising
- pressurizing a cleaning solution from the dialysate side of the hemodialyzer,
- passing a premixed mixture of a liquid and a gas into the lumen side of the hemodialyzer,
- combining said cleaning solution and said liquid-gas mixture so as to generate droplets that create shear or impact stresses that sweep the interior walls of the hemodialyzer fibers to remove the contaminant.

50. (Original) A method according to claim 49 wherein the cleaned dialyzer is rinsed with deionized water and filled with a liquid sterilant.
51. (Original) A method according to claim 49 wherein the cleaning solution and the liquid used to form the liquid-gas mixture are the same.
52. (Original) A method according to claim 49 wherein the cleaning solution and the liquid used to form the liquid-gas mixture are different.
53. (Currently Amended) A method according to claim 49 wherein the liquid used to form the liquid-gas mixture includes an agent that unclogs the lumens of the hollow fibers of the hemodialyzer dialyzer.
54. (Original) A method according to claim 53 wherein said agent is selected from the group consisting of heparin and a citrate solution.
55. (Original) A method according to claim 49 wherein said cleaning solution includes a chelating agent.
56. (Original) A method according to claim 49 wherein said cleaning solution includes a surfactant.
57. (Original) A method according to claim 49 wherein said cleaning solution has a pH of at least 7.0.
58. (Original) A method according to claim 49 wherein said cleaning solution includes a peroxy compound oxidizing agent, said solution having an acid pH.
59. (Original) A method according to claim 49 wherein said cleaning solution includes a hypochlorite compound oxidizing agent.
60. (Original) A method according to claim 49 wherein said cleaning solution includes sodium hydroxide.
61. (Original) A method according to claim 49 wherein said cleaning solution has a temperature of from 20 to 60 degrees Centigrade.

62. (Currently Amended) A method according to claim 49 wherein the direction of the liquid-gas mixture ~~two-phase flow~~ is periodically reversed.
63. (Currently Amended) A method according to claim 49 wherein the liquid-gas mixture ~~two-phase flow~~ cleaning is preceded with a backflushing the lumen side using a cleaning solution alone.
64. (Currently Amended) A method according to claim 49 wherein the liquid-gas mixture ~~two-phase flow~~ cleaning is followed by backflushing the lumen side using a cleaning solution alone.
65. (Original) A method of removing contaminants from the lumen and under-the-cap regions of a hemodialyzer including hollow fibers comprising
- passing a pre-mixed mixture of a cleaning solution and a gas into the lumen side of the hemodialyzer so as to generate droplets that create shear or impact stresses on the lumen walls of the hollow fibers, and wherein said mixture creates turbulence inside the under the cap regions of the hemodialyzer, thereby loosening and removing said contaminants from the hemodialyzer.
66. (Original) A method according to claim 65 wherein the cleaned hemodialyzer is rinsed with deionized water.
67. (Original) A method according to claim 65 wherein said cleaning solution includes a chelating agent.
68. (Original) A method according to claim 65 wherein said cleaning solution includes a surfactant.
69. (Original) A method according to claim 65 wherein said cleaning solution has a pH of at least 7.0.
70. Cancelled
71. (Original) A method according to claim 65 wherein said cleaning solution includes a hypochlorite compound oxidizing agent.

72. (Original) A method according to claim 65 wherein said cleaning solution includes sodium hydroxide.
73. (Original) A method according to claim 65 wherein the temperature of said cleaning solution is in the range of 20 to 60 degrees Centigrade.
74. (Original) A method according to claim 65 wherein the direction of the two-phase flow is periodically reversed.
75. (Original) A method according to claim 65 wherein the two-phase flow cleaning is preceded by backflushing using a cleaning liquid alone.
76. (Original) A method according to claim 65 wherein the two-phase flow cleaning is followed by a backflushing using a cleaning liquid alone.

77-93. Cancelled

94. (New) A method for cleaning a hemodialyzer having a housing, a bundle of hollow permeable membrane fibers within the housing, a dialysate side inlet and outlet, and a lumen side inlet and outlet, the method comprising steps of:

- (a) pressurizing a liquid cleaning solution in the dialysate side to infiltrate the liquid cleaning solution into the lumen side, and
- (b) passing a gas into the lumen side to form a two phase flow of the gas and the liquid cleaning solution in the lumen side.

95. (New) A method according to claim 94, wherein the hollow permeable membrane fibers comprise ultrafiltration membranes.
96. (New) A method according to claim 94, wherein the hollow permeable membrane fibers comprise nanofiltration membranes.
97. (New) A method according to claim 94, wherein the hollow permeable membrane fibers comprise reverse osmosis membranes.

98. (New) A method according to claim 94, wherein the gas is applied to the lumen side at a velocity of 10 ft/sec to 500 ft/sec.
99. (New) A method according to claim 94, wherein droplets are formed within the lumen side.
100. (New) A method according to claim 99, wherein the droplets have a diameter of about 20 microns and higher.
101. (New) A method according to claim 99, wherein the droplets have a diameter of 50 microns to 250 microns.
102. (New) A method according to claim 94, wherein the liquid cleaning solution to gas ratio in the lumen side is between 1:50 and 1:6,000.
103. (New) A method according to claim 94, wherein the cleaned hemodialyzer is rinsed with deionized water and filled with a liquid sterilant.
104. (New) A method according to claim 94, wherein said liquid cleaning solution includes a chelating agent.
105. (New) A method according to claim 94, wherein the liquid cleaning solution is made with sodium hydroxide.
106. (New) A method according to claim 94, wherein the liquid cleaning solution has a temperature in the range of 20°C to 60°C.
107. (New) A method according to claim 94, wherein the liquid cleaning solution includes a surfactant.
108. (New) A method according to claim 94, wherein the liquid cleaning solution has a pH of at least 7.0.
109. (New) A method according to claim 94, wherein the liquid cleaning solution includes a peroxy compound having an acidic pH.

110. (New) A method according to claim 94, wherein the liquid cleaning solution includes a hypochlorite.
111. (New) A method according to claim 94, wherein the two phase flow is pulsed.
112. (New) A method according to claim 94, comprising applying a pre-mixed liquid-gas two phase flow mixture to the lumen side.
113. (New) A method for cleaning a hemodialyzer having a housing, a bundle of hollow permeable membrane fibers within the housing, a dialysate side inlet and outlet, and a lumen side inlet and outlet, the method comprising:
- (a) passing a mixture of a liquid and gas into the lumen side of the hemodialyzer.
114. (New) A method according to claim 113, further comprising pressurizing a cleaning solution in the dialysate side of the hemodialyzer.
115. (New) A method according to claim 114, wherein the cleaning solution and the liquid used to form the liquid-gas mixture are the same.
116. (New) A method according to claim 114, wherein the cleaning solution and the liquid used to form the gas-liquid mixture are different.
117. (New) A method according to claim 113, wherein the hollow permeable membrane fibers comprise ultrafiltration membranes.
118. (New) A method according to claim 113, wherein the gas is applied to the lumen side at a velocity of 10 ft/sec to 500 ft/sec.
119. (New) A method according to claim 113, wherein droplets are formed within the lumen side.
120. (New) A method according to claim 121, wherein the droplets have a diameter of about 20 microns and higher.

121. (New) A method according to claim 121, wherein the droplets have a diameter of 50 microns to 250 microns.

Support for Amendments

The above amendment cancels nonelected claims 24-34 and 77-93.

Several of the pending claims are amended to correct antecedence. For example, claim 46 is amended to refer to "gas." Claim 48 is amended to refer to a "cleaning solution." Claim 53 is amended to refer to a "hemodialyzer." Claims 62-64 are amended to refer to the "liquid-gas mixture" rather than a "two phase flow." In addition, claims 63 and 64 are amended to more clearly reflect a step of backflushing the lumen side using a cleaning solution alone. This is supported by the specification at, for example, page 22, lines 3-9 and page 20, line 18 through page 21, line 7.

New independent claim 94 is supported by the specification at, for example, page 12, line 20 through page 13, line 11. New independent claim 113 is supported by the specification at, for example, page 13, lines 12-19. It is pointed out that the characterization of the hemodialyzer being cleaned is supported by the characterization of the hemodialyzer described by the specification at page 19, lines 1-8.

New claims 95-97 and 117 are supported by the specification at page 18, lines 6-12.

New claims 98 and 118 are supported by the specification at page 19, lines 16-17.

New claims 99-101 and 119-121 are supported by the specification at page 19, line 17 through page 20, line 3.

New claim 102 is supported by the specification at page 20, lines 4-5.

New claims 103-110 are based upon presently pending claims 36 and 38-44.

New claim 111 is supported by the specification at page 20, lines 18-19.

New claim 112 is supported by the specification at, for example, page 13, lines 12-15.

New claim 114 is supported by the specification at, for example, page 22, line 18 through page 23, line 2.

New claims 115 and 116 are supported by the specification at, for example, page 23, lines 3-5.

In view of the above comments, no new matter is introduced by this amendment, and entry thereof is requested. Upon entry, claims 35-76 and 94-121 are active in this application.